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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,050	10/30/2003	Orhan Soykan	P-10120.00	1185

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EXAMINER	
WINAKUR, ERIC FRANK	
ART UNIT	PAPER NUMBER
3768	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/698,050	SOYKAN ET AL.	
	Examiner	Art Unit	
	Eric F. Winakur	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *22-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/14/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim does not recite a positive method step, and therefore is not further limiting.

Claim Rejections - 35 USC § 101

3. Claims 11 - 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 11 recites "additionally at least one of said light emitter or said light detector is also implanted in the body" which improperly includes a portion of a living being ("the body") as part of the claimed structure. The claim should recite "... is also adapted to be implanted ..." to avoid including the body as part of the claimed subject matter. In addition, claim 18 also must be similarly amended to avoid including the body as part of the claimed subject matter.

Claim Rejections - 35 USC § 103

4. Claims 1 - 8, 10, 11, 13 - 16, 19 - 21, and 33 - 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. in view of Van Antwerp et al. Chick et al. teach a method and arrangement for detecting an analyte in the human body comprising placing an analyte detector with two fluorescent dyes within the body, illuminating the detector, and measuring the analyte concentration based upon the ratio

of energy emitted by the two dyes as a result of fluorescent resonant energy transfer (FRET) between them (col. 2, line 31 - col. 6, line 44). Further, a drug delivery system in communication with the analyte detector may be implanted in the body such that a feedback loop is established wherein a prescribed amount of drug is released when the measured analyte concentration exceeds a certain threshold (col. 6, lines 1-5). The illuminating energy is visible light at a wavelength of 472 nm (col. 11, lines 36-47) and the analyte measured may be a protein in the blood (the level of which may vary under certain physiological states) or an antigen or a narcotic such as cocaine or heroin (col. 5, lines 15-50). Chick et al. teaches an implantable sensor with transdermal determination of analyte concentrations (column 6, lines 6 - 34; column 16, line 23 - column 17, line 32). Van Antwerp et al. (Figure 6 and the description thereof) teach an alternate arrangement that includes completely implantable emitter, detector, and sensing elements. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to use a completely implantable arrangement, as taught by Van Antwerp et al., since this is merely an alternate equivalent expedient.

It is noted that Applicant's remarks, page 10, are relevant to the above recited combination. In essence, Applicant alleges that the combination fails because Van Antwerp et al. is not a FRET-based system, and therefore cannot suggest the desirability of a completely implanted FRET-based system. However, this is not persuasive, as the teaching of Van Antwerp et al. discloses that a totally implanted optical measurement system is an alternative to an implanted system and possesses

certain advantages. One of ordinary skill in the art would recognize that these advantages are equally relevant to problems one would identify in a FRET-based measurement arrangement. Contrary to Applicant's assertions, the teaching of Van Antwerp et al. is relevant to the problems one would encounter with the system of Chick et al. and teaches a solution that would be within the skill in the art to implement therewith.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. and Van Antwerp et al. as applied to claim 1 above, and further in view of Wicks et al. and Khaw et al. Chick et al. in view of Van Antwerp et al. teach all of the features of the invention except that the sensed protein is troponin-T antigen. Wicks et al. teach that troponin I is a protein that is a marker for cardiac damage (column 1, lines 24 - 41). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement Chick et al. with sensitivity for troponin, since Chick et al. teach that their method and arrangement are suitable for detecting proteins in the blood that are indicative of physiological states (column 9, line 59 - column 12) and Wicks et al. teach that troponin I is a blood protein that is a marker for cardiac damage. Further, Khaw et al. teach that troponin I and T are alternate equivalents for sensing heart attack related events (paragraphs [0002] and [0011]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to sense troponin T, since Khaw et al. teach that this is an alternate equivalent expedient to troponin I and it has generally been held to be within the skill level of the art to substitute alternate equivalent expedients.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. and Van Antwerp et al. as applied to claim 11 above, and further in view of Kwon. The combination teaches all of the features of the claimed invention except for the particularly claimed fluorescent dyes. Kwon teaches monitoring analyte concentrations in the body using FRET, wherein one of the dyes which may be used is tetramethylrhodamine isothiocyanate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use with the FRET system disclosed by the combination with the fluorescent dye tetramethylrhodamine isothiocyanate, since Kwon teaches that this dye allows for effective FRET analyte concentration measurements.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. and Van Antwerp et al. as applied to claim 11 above, and further in view of Rao et al. The combination teaches all of the features of the claimed invention except that there is an alert module. Rao et al. teach an alternate FRET system that includes an alert module to notify a subject of changes in concentration (see Figure 9 and the description thereof). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to include an alert module, as taught by Rao et al., since this allows a subject to be notified of changing concentrations.

8. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. and Van Antwerp et al. as applied to claim 1 above, and further in view of Wicks et al. Chick et al. teach all of the features of the invention except that the sensed protein is troponin. However, Wicks et al. teach that troponin I is a protein that is a marker for

cardiac damage (column 1, lines 24 - 41). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement Chick et al. with sensitivity for troponin, since Chick et al. teach that their method and arrangement are suitable for detecting proteins in the blood that are indicative of physiological states and Wicks et al. teach that troponin I is a blood protein that is a marker for cardiac damage.

Response to Arguments

9. Applicant's arguments with respect to claims 1 - 21 and 33 - 37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric F Winakur
Primary Examiner
Art Unit 3768